ANNEXURE 1

POST-IMPORTATION TESTING OF STOCK REMEDIES (ACT 36/1947)

The integrity of imported stock remedies, both pharmaceutical and biological, may be compromised during the importation process. It is therefore important that the applicant retest the product or validate/ verify the integrity of the transport procedure, once marketing authorisation has been obtained. If local testing is not viable, the applicant will be required to include, a request for exemption from post-importation testing in the registration dossier. This should include an undertaking to validate/ verify the transport process. Proof of transport validation/verification will not be required to be submitted however this must be kept on record for reference purposes should information become available suggesting that the transport process has been compromised or as deemed necessary by the authorities as stipulated by Section 16 (3) of the Act. Revalidation/verification will be required only if there is a change in the process.

One of the following options may be exercised:

a) **Importation Monitoring:** monitoring and control of transport i.e provision of evidence that the conditions during transport are continuously monitored and controlled, and including relevant parameters, such as temperature, humidity, vibration and freeze.

OR

b) **Post Importation Testing**: performance identification and assay/titre testing at a local laboratory.

a) IMPORTATION MONITORING

The following must be taken into consideration:

i) A process of formal verification should be followed for transportation of the stock remedy. Documented proof must be available for inspection.

ii) Calibrated temperature monitoring devices (both minimum and maximum) must be placed inside the container to record the conditions whilst the product is in transit. These should be recorded by a suitable device which provides a printout providing a permanent record of the specific shipment to be filed with the batch release documents

iii) If the stock remedy is sensitive to vibrations/agitation, it must be transported under vibration/agitation-controlled conditions.

iv) An SOP, specifying the details of inclusion of the recorders, should be available for inspection. The procedure should include, amongst other details, the number of recorders, position of placement, date/time of activation and inactivation (on leaving the place of dispatch (e.g. factory, and on receipt by the applicant, e.g. warehouse) and evaluation of the printout with the reference to the stability data.

v) The monitoring and control mechanism should be qualified and/or calibrated by the supplier as applicable, and relevant documents made available for inspection. Thermo logger locations must be scientifically justified. Vibration studies ensuring that physical stresses encountered during transport do not negatively affect stress- sensitive products and detailing the control of vibrations during transportation, must be submitted.

vi) A tabulated summary must be compiled indicating the following

- the method of transport,
- the conditions during transport as indicated below, and the method of controlling the respective conditions.
- The type of recorder used in transit.
- Specification that the received certificate of analysis is valid, is complete (reflects the actual results of the tests performed) and reflects compliance with the registration requirements
- Visual identification of the product and dosage form
- A consignment reference e.g. GRN (goods received notice) or invoice. Batch numbers on the invoice should concur with the batch numbers of the products.

- Confirmation of the integrity of the containers, seals, and labels. Each aspect should be specified and controlled to ensure that no damaged articles are accepted.
- Outcome of the evaluation of the transport conditions, and relevant action to be performed, i.e. further testing.
- Evidence to support that the product imported has not been subjected to transport delays/repackaging that may result in tampering / counterfeiting of the imported product.

Receiving Date:
Registration number (Act 36/1947):
Dosage form:
Approved storage conditions:
Assurance: Temperature recorded in the shipment
Temperature Logger Serial numbers:

GRN/ Invoice No.	Batch No.	Product Name, Strength and pack size	Registration No. (Act 36/1947)	Maximum and minimum temperature recorded *	Other transport sensitive conditions e.g. vibration measurements	Maximum humidity recorded (where relevant) *	Duration of transport (Date commenced and date terminated)	Mode of Transport	Product Container integrity	Signature of Responsible Person who verified the information

* Data printouts attached

vii If an out of specification result is recorded revert to option (b)

b) POST-IMPORTATION TESTING

If option (b) is exercised by the applicant, the following should be taken into consideration:

i) The stock remedy must be transported under appropriate conditions.
ii) An accredited laboratory must be available locally to do the testing
iii) A validated method of analysis is used by the laboratory and must be available for inspection
iv) A tabulated summary must be compiled indicating the following.:

- the method of transport,
- Specification that the received certificate of analysis is valid, complete (reflects the actual results of the tests performed) and reflects compliance with the registration requirements
- Specification that the control laboratory certificate of analysis is valid, complete (reflects the actual results of the tests performed) and reflects compliance with the registration requirements
- A statement reflecting visual identification of the product and dosage form
- A consignment reference e.g. GRN (goods received notice) or invoice. (Batch numbers on the invoice should concur with the batch numbers of the products).
- Confirmation of the integrity of the containers, seals, and labels. Each aspect should be specified and controlled to ensure that no damaged articles are accepted.
- Outcome of the evaluation of the analyses and relevant action, e.g. further testing to be performed.
- Evidence to support that the product imported is not subject to transport delays/repackaging that may result in tampering / counterfeiting of the imported product.

Registration of Stock Remedies
Pharmaceutical & Analytical
Name of product:
Registration Number (Act 36/1947):
Dosage Form:
Approved storage conditions:
Assurance: Analysis through local laboratory

GRN/ Invoice No.	Batch No.	Analysis results from Laboratory at origin*	Analysis results from local Laboratory *	Duration of transport (Date commenced and date terminated)	Mode of Transport	Product Container integrity	Signature of Responsible Person who verified the information

* Certificates of analysis attached